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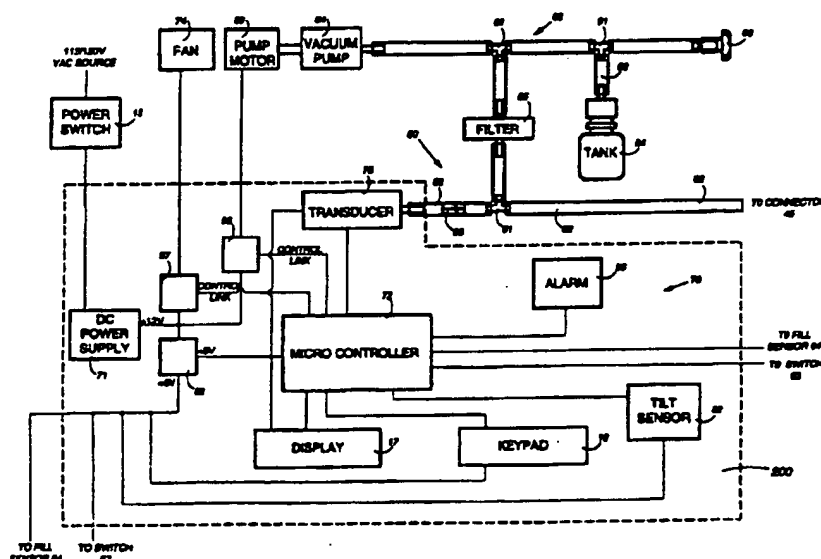


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(54) Title: WOUND DRAINAGE EQUIPMENT



(57) Abstract

A therapeutic apparatus is disclosed for stimulating healing of a wound in mammals. The apparatus comprises a porous foamed pad (36) connected by a tube (37, 38) to a canister (19). A vacuum pump is located within a housing having a recess (18) for receiving the canister. A bacterial filter (46) positioned over the outlet of the canister protects the vacuum pump from contamination by wound drainage fluids sucked into the canister.

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WOUND DRAINAGE EQUIPMENT

The present invention relates to the healing of wounds and, more particularly, but not by way of limitation, to an apparatus for closing wounds that is compact, self-contained, and includes a disposable wound fluids canister.

Wound closure involves epithelial and subcutaneous tissue adjacent the wound migrating towards the centre of the wound until it closes. Unfortunately, closure is difficult with large wounds or wounds that have become infected. In such wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound. Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but are also less able to successfully fight bacterial infection and, thus are less able to close the wound naturally. Such wounds have presented difficulties to medical personnel for many years.

The most common technique for closing open wounds has been the use of sutures or staples. Although such mechanical closure techniques are widely practised and often effective, they suffer a major disadvantage by providing tension on the skin tissue adjacent the wound. That is, the tensile force required to achieve closure using sutures or staples causes very high localized stresses at the suture or staple insertion point. Such stresses commonly result in the rupture of the tissue at those points, which can eventually cause dehiscence in wounds, providing additional tissue loss.

Moreover, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalisation,

with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds, decubitus ulcers, ulcers resulting from chronic osteomyelitis, and partial thickness burns that subsequently develop into full thickness burns.

The above problem is discussed in WO 93/09727 which proposes as a solution a procedure for draining the wound by applying a continuous negative pressure to the wound over an area sufficient to promote migration of epithelial and subcutaneous tissue toward the wound. Although WO 93/09727 deals in some detail with the clinical considerations of this kind of treatment, the apparatus described has certain practical shortcomings.

One problem with the apparatus described in the above prior document is that no means are disclosed for avoiding spread of infection from one patient to another or re-infection of the patient being treated.

In accordance with the present invention, there is provided a therapeutic apparatus for stimulating healing of wounds, said apparatus including a housing that contains a vacuum pump and a chamber for holding a disposable wound drainage collection canister. The canister preferably resides within the chamber and connects at an outlet with the vacuum pump and at an inlet with a porous pad. The pad is placed over a wound and adhesively secured thereto to create a sealed environment at the wound. Thus, when the vacuum pump activates, it evacuates air from the canister and thence the wound environment, resulting in the application of negative pressure to the wound, which in turn tends to promote drainage of fluids flowing from the wound into the canister. After the canister is filled, it is removed from the chamber, disposed of, and replaced with another canister to continue therapy.

Although the vacuum pump is designed to be reusable because of its more costly components, the apparatus utilizes a removable and disposable canister adapted to prevent contamination of the vacuum pump or the remainder of the apparatus. If the vacuum pump or other parts of the housing or the tubing leading to the pump from the canister became contaminated, the wound closure apparatus would have to be completely disassembled, thoroughly cleaned and possibly discarded. Disassembly and cleaning of the wound closure apparatus is extremely time and labour intensive, while disposal of the wound closure apparatus is expensive. Consequently, a removable and disposable canister prevents either of the above undesirable circumstances from occurring.

It is, therefore, an object of the present invention to provide a wound closure apparatus that closes wounds without stressing the surrounding skin.

It is another object of the present invention to render technology like that disclosed in WO 93/09727 available in a convenient, compact and self-contained, efficient and economically feasible system. It is also an object to optimize the safety and effectiveness of such a device, particularly from an infection control standpoint.

It is a further object of the present invention to provide a wound closure apparatus that includes a removable and disposable wound fluids collection canister to protect the wound closure apparatus from contamination.

Still other objects, features and advantages of the present invention will become evident to those skilled in the art in light of the following.

Figure 1 is a perspective view depicting the vacuum pump unit of a wound closure apparatus constructed according to the teachings of the present invention.

Figure 2 is a right side plan view depicting the vacuum pump unit of Figure 1.

Figure 2A is a detail view of the latch 26 portion of Figure 2, partially cut-away to eliminate guide (or "key") 29 from the view and to show portions of latch 26 in sagittal cross section.

Figure 3 is a perspective view depicting a wound drainage collection canister for use in conjunction with the vacuum pump unit of Figure 1.

Figure 4 is a rear plan view depicting the wound drainage collection canister of Figure 3.

Figure 5 is a perspective view depicting the connection of a wound drainage collection canister of Figure 3 to a wound pad.

Figure 6 is a front plan view in partial cross section depicting the connection of the wound drainage collection canister of Figure 3 within the housing of the vacuum pump of Figure 1.

Figure 6A is a partial view of the apparatus shown in Figure 6 except the canister is removed.

Figure 7 is a perspective view depicting the filter carrier of the wound drainage collection canister.

Figure 8 is a top plan view depicting the filter cap of the wound drainage collection canister.

Figure 9 is a schematic view depicting the control system for a wound closure apparatus constructed according to the teachings of the present invention, and

Figure 10 is a section through a wound showing the wound pad in place.

As illustrated in Figures 1 and 2, front housing 11 and rear housing 12 connect together using any suitable means such as screws and fasteners to

provide wound closure vacuum pump 10 with a small, compact, and easily portable carrying case. Consequently, front housing 11 and rear housing 12 connect together to form handle 13 that permits easy carrying of wound closure apparatus 10. Except as maybe otherwise evident from this description, the carrying case of vacuum pump 10 is substantially as described and shown in WIPO Design No. DM/032185.

Front housing 11 includes power switch 15 that is movable between an on and off position to permit user control of the delivery of power to wound closure apparatus 10. Keypad 16 and liquid crystal display (LCD) 17 mount to front housing 11 to permit the programming of wound closure apparatus 10. Chamber 18 is defined by integrally formed interior side walls 100 and 101, top wall 102, bottom wall 103 and rear wall 104. Side wall 100 is dependently attached to the interior of front housing 11 by standard mounting hardware (not shown). The wound fluids collection canister, illustrated in Figures 3-5, is received within chamber 18. Side walls 100 and 101 each include a key 29 and 30, respectively, the aid in the alignment of wound fluids collection canister 19 within chamber 18. Furthermore, front housing 11 includes latch 26 to secure the wound fluids collection canister within chamber 18.

Rear housing 12 includes arm 14 pivotally mounted to it within recess 110. An identical arm pivotally mounts to the opposite side of rear housing 12 within an identical recess. Arm 14 and its corresponding arm mounted on the opposite side of rear housing 12 pivot from within their recesses to a position where they support wound closure apparatus 10 at an angle. Arm 14 and its corresponding arm angularly support wound closure apparatus 10 to permit easier user access to keypad 16. Arm 14 and its corresponding arm may also be used to permit hanging of apparatus 10 from a hospital bed foot board.

Canister 19 has a shape as shown in Figures 3 to 6. As illustrated in Figures 3 to 6, canister 19 includes sidewalls 20 and 21, top wall 23, bottom wall 24, back wall 22 and front wall 25 that define the rectangular chamber for receiving blood, pus, and other fluids emitted from a wound. Sidewalls 20 and 21 include keyways 27 and 31 respectively, that receive a respective one of keys 29 and 30 to provide easy alignment of canister 19 within chamber 18. Furthermore, keyway 27 includes recess 28 that receives latch 26 to fasten canister 19 within chamber 18.

Front wall 25 of canister 19 includes raised portion 32 extending therefrom to furnish a window that permits a user to determine the level of wound fluids within canister 19. Accordingly, raised portion 32 is transparent so that the level of wound fluids within canister 19 may be visually determined. Raised portion 32 includes sidewalls 110 and 111, top wall 112, bottom wall 113, and front face 114 that define a chamber which opens into the chamber defined by sidewalls 20 and 21, top wall 23, bottom wall 24, back wall 22 and front wall 25 of canister 19. Front face 114 of raised portion 32 includes graduations that demarcate the volume of wound fluid within canister 19. Additionally, sidewalls 110 and 111 of raised portion 32 include ridges that provide a gripping surface for the user during the insertion and removal of canister 19 from chamber 18.

Although raised portion 32 is transparent to permit the determination of the level of wound fluids within canister 19, sidewalls 20 and 21, back wall 22, top wall 23, bottom wall 24, and front wall 25 are opaque or textured so that they are only translucent. As an alternative, the portions of canister 19 surrounding filter 46 may also be transparent. This enables a user to visually check for signs of contamination of filter 46. In this preferred embodiment,

sidewalls 20 and 21, back wall 22, top wall 23, bottom wall 24, front wall 25, and raised portion 32 of canister 19 are fabricated from a plastics material.

Canister 19 includes inlet 35 that is formed integrally with top wall 112 of raised portion 32. Inlet 35 is cylindrical in shape and communicates with the interior of canister 19 to permit the transfer of wound fluids into canister 19. In this preferred embodiment, inlet 35 is also fabricated from a plastics material.

In order to prevent liquids sucked into the canister from splashing directly onto cap 49, which masks the outlet 44, and to reduce foaming within the canister, inlet 35 has a blind inner end. Inlet 35 has a slot 35A so that drainage fluid is deflected downwardly into the raised handle portion 32 of the canister. Handle portion 32 may communicate with the main part of the canister through one or more holes in wall 25. It is desirable to avoid foaming because this can give a false reading when a capacitance sensing device is used to sense when the canister is filled. An anti-foaming material, e.g. a silicone may be added to the canister, e.g. by coating the interior walls. It may also be advantageous to include a gel-forming substance, e.g. a polyacrylamide or modified starch in order to immobilise the drainage fluid. This is particularly useful if the apparatus is likely to be tilted.

Wound fluids (i.e. drainage) are communicated through inlet 35 into canister 19 via pad 36 and hoses 37 and 38. In this preferred embodiment, pad 36 is fabricated from an open cell polyurethane or polyether foam. Hose 37 is inserted within pad 36 by making an incision in pad 36 and inserting the end of hose 37. Hose 37 can then be secured within pad 36 using any suitable means such as an adhesive or a flange. Preferably, the foam pad is moulded or formed with an elongated hole for the drainage tube which is an interference fit with the tube. The hoses are preferably made from medical grade PVC tube. Hose 38

mounts within inlet 35 using any suitable means such as an adhesive or welding. Hoses 37 and 38 include luer lock connectors 39 and 40, respectively, (or the equivalent such as any known quick disconnect type coupling) that attach together to permit communication between hoses 37 and 38. Furthermore, hoses 37 and 38 include pinch clamps 41 and 42, respectively, that are capable of sealing their respective hose 37 or 38 to prevent the flow of wound fluids. The foam pad is preferably packaged in a sterile container together with its connector and clamp. When packaged, the clamps will be in their open condition.

The communication of wound fluids into canister 19 requires the securing of pad 36 over a wound. Pad 36 is secured over a wound using cover 43 which is fabricated from a plastics material and includes an adhesive on one side that sticks to human skin. Wound cover 43 is conveniently a surgical drape material comprising a sheet of elastomeric material coated peripherally or overall with a pressure-sensitive adhesive, such as an acrylic adhesive. The elastomeric or rubbery nature of the wound cover is important because it accommodates changes in pressure in the wound area during intermittent operation of the vacuum pump. The wound cover is preferably a polyurethane film with a removable backing sheet, i.e. of polythene to protect the adhesive surface.

A high degree of reticulation in the polymer foam is desirable to achieve good permeability when the foam is under suction. Foams having at least 90% and especially at least 95% of interconnecting cells are preferred.

In use, the foam pad is cut to a size which corresponds closely to the edge of the wound with the objective of packing the foam into the wound cavity 210 so that it contacts the surface of the cavity, rather than bridging the cavity.

As depicted in Figure 10, the cavity may be extensive and there may be little or no tissue coverage to the bone 212. This is illustrated diagrammatically in Figure 10. Figure 10 is a cross-section through a wound showing the foam pad 36 packed into the wound cavity 210. It is important that the foam should be firmly packed into the recesses of the wound cavity. Drainage tube 37 terminates within the centre of the foam pad 36. Surgical drape 43 extends over the foam pad and is adhered to intact skin 211 around the periphery of the wound. Drape 43 is also firmly adhered around the tube 37 to prevent leakage of air. A wound cover is then adhered to the surrounding skin and around the drainage tube to provide an air-tight seal around the wound.

As illustrated in Figures 2, 4 and 6, canister 19 includes outlet 44 that mounts over port 45 to permit wound closure apparatus 10 to draw wound fluids into canister 19. Outlet 44 is cylindrically shaped and formed as an integral part of back wall 22 by outer wall 33 and inner wall 50 which are interconnected by end wall 34. Passageway 52, defined in part by interior wall 50 and in part by filter cap 49, provides the actual conduit for outlet 44 between the interior and exterior of canister 19. The placement of canister 19 within recess 18 such that outlet 44 resides over port 45 couples canister 19 to a vacuum pump. The vacuum pump removes air from canister 19 to create vacuum pressure within canister 19. That vacuum pressure is then transmitted to a wound site through hoses 37 and 38, thereby not only enabling therapeutic use of system 10, but also tending to promote wound drainage. Any wound drainage fluid is then drawn through pad 36 and hoses 37 and 38 into canister 19.

Outlet 44 resides near top wall 23 of canister 19 to ensure efficient operation of the vacuum pump. That is, the vacuum pump removes the most

air from canister 19 when the air does not have to first bubble through wound fluids contained in canister 19. Consequently, with outlet 44 positioned near the top of canister 19, the vacuum pump removes air directly from canister 19, and it is only during the final filling of canister 19 that air must bubble through wound fluids. Preferably, as described below, the apparatus includes detecting and warning means which operates before the level of the drainage fluid reaches either the inlet or outlet tube so that a fresh canister can be installed.

In removing fluids from a wound utilizing wound closure apparatus 10, a major safety concern is preventing wound fluids from contaminating the vacuum pump. Accordingly, filter 46 mounts over outlet 44 utilizing filter carrier 48 and filter cap 49 to block the flow of wound fluids to outlet 44 so that wound fluids remain within canister 19 and do not flow into the vacuum pump. In this preferred embodiment, filter 46 is a 0.2 micron hydrophobic membrane filter providing a bacterial barrier, although other filters may be substituted as appropriate.

As illustrated in Figure 7, filter carrier 48 includes face 53 formed integrally with lip 54. Face 53 includes groove 56 formed therein, while lip 54 supports brace 55 in its interior. Filter 46 fits within groove 56 of face 54 and is supported within filter carrier 48 by brace 55 of lip 54. An 'O' ring 53A is fitted in peripheral recess of filter carrier 48 to accommodate manufacturing tolerances and ensure a fluid tight seal in filter cap 49.

As illustrated in Figures 6 and 8, filter cap 49 includes cylindrical portions 57 and 58 which are formed integrally (with annulus 57 spanning therebetween), to hold filter carrier 48 within passageway 52 of outlet 44. To mount filter 46 over passageway 52, filter 46 is first placed within filter carrier 48 as described above. Filter carrier 48 is then positioned within filter cap 49

such that face 53 abuts annulus 57' of filter cap 49 and lip 54 of filter carrier 48 resides within annular lip 50' of outlet 44. Accordingly, when cylindrical portion 57 of filter cap 49 mounts over outlet 44, the front face 53 of filter carrier 48 and the outer edges of filter 46 abut annulus 57' to secure filter 46 within passageway 52. Filter cap 49 attaches to outlet 44 using any suitable means such as an adhesive or welding. Filter cap 49 is completely sealed except for aperture 51 positioned on top of filter cap 49. Aperture 51 communicates with port 45 via passageway 52 of outlet 44 to permit the vacuum pump to draw air from the interior of canister 19.

As illustrated in Figures 2 and 6, port 45 includes O-ring 59 mounted thereabout to provide a fluid tight seal between port 45 and inner wall 50 of outlet 44. Port 45 mounts through rear wall 104 of chamber 18 using any suitable means such as nuts 60 and 61. Furthermore, hose 62 attaches to the rear of port 45 using any suitable means such as a clamp to couple port 45 to the vacuum pump.

Switch 63 protrudes through rear wall 104 of chamber 18 to produce a signal indicating when canister 19 properly and securely resides within chamber 18. In this preferred embodiment, switch 63 is a normally open push button switch that mounts on rear wall 104 of chamber 18 using any suitable means such as a bracket. When canister 19 is properly positioned within chamber 18, its rear wall 22 presses the head of switch 63, closing switch 63 so that it provides a signal indicating that canister 19 properly resides within chamber 18.

Fill sensor 64 resides adjacent side wall 101, exterior to chamber 18. Fill sensor 64 provides a signal that indicates when canister 19 is filled with wound debris. In this preferred embodiment, fill sensor 64 is a capacitive sensor that mounts on side wall 101 of chamber 18 using any suitable means such as a

bracket or appropriate adhesive material. Fill sensor 64 has a sensing profile 64A which determines the point at which the capacitance measurement is made. When wound fluids have reached the level within canister 19 which corresponds to the location of the sensing profile 64A, the capacitance within canister 19 as 'seen' by fill sensor 64 changes, resulting in fill sensor 64 outputting a signal indicating that canister 19 is filled with wound fluids to the level at which the sensing profile is located. The position of this sensing profile behind wall 101 can be changed (see Figure 6A) to provide an optimum balance of space and volume utility.

As illustrated in Figure 2A, latch 26 generally comprises latch pin 65, handle 66 latch guide sleeve 68A and spring 67. Latch pin 65 comprises a proximal end 65A and distal end 65B. Latch guide sleeve 68A abuts the inner surface of front housing 11 and is held securely in place from the outer side of front housing 11 by nut 68B. Handle 66 screws onto the proximal end 65A of latch pin 65 and is locked in position by nut 69A. In the preferred embodiment, cover 68 over nuts 69A and 68B provides a surface against which handle 66 abuts, thus preventing end 65B from excessively entering chamber 18 as will be understood further herein. Cover 68 also provides aesthetic enclosure of nuts 69A and 68B. Dependent attachment of side wall 100 (chamber 18), as described hereinabove, is such that side wall 100 abuts latch guide sleeve 68A on the side distal front housing 11. Further, this arrangement causes distal end 65B of latch pin 65 to project into chamber 18 under the force of spring 67 (shown partially cut away). Spring 67 resides circumferentially about latch pin 65 within an axial bore of latch pin guide 68A. Spring 67 exerts force between distal end 65B of latch pin 65 and an annulus within the axial bore of latch pin guide 68A. A transverse slot in the distal end of latch pin guide 68A receives

end 65B of latch pin 65, providing rotational alignment of end 65B and further recess for end 65B when a user "pulls" handle 66 in an axial direction.

Latch 26 operates to ensure canister 19 remains secured within chamber 18. End 65B of latch 26 terminates in a point that protrudes through key 29 into chamber 18. During the placing of canister 19 within chamber 18, key way 27 of canister 19 forces the point 65B of the latch pin within key 29. However, once canister 19 has been properly positioned within chamber 18, recess 28 resides below latch pin end 65B so that spring 67 biases the point 65B of latch pin 65 into recess 28 to prevent the removal of canister 19 from chamber 18. The removal of canister 19 from chamber 18 is accomplished by grasping handle 66 and pulling the point 65B of latch pin 65 from recess 28. With the point of latch pin 65 no longer within recess 28, canister 19 may be pulled from chamber 18 using its raised portion 32.

As illustrated in Figure 9, wound closure apparatus 10 preferably plugs into a standard 115/120 VAC power source (e.g. an outlet) to supply power to control system 70. Alternative embodiments (not shown, although similar) are readily adapted for 220 VAC power by changing the power cord and appropriately re-wiring the tops of the transformer within the DC power supply 71 as is readily known in the art. The application of power to control system 70 is regulated by power switch 15 which is a standard push button on/off switch. With power switch 15 depressed, DC power supply 71 receives the 115/120 VAC signal and converts it into a 12 VDC signal for use by fan 74 and motor 83. A conventional voltage regulator 96 steps down the voltage to +5V or 12V for use by each of the other DC components 63, 16, 17, 82, 72 and 75. Voltage regulator 96 connects to keypad 16, LCD 17, switch 63, microcontroller 72, transducer 75, and tilt sensor 82 to supply each of them with the +5V DC

signal. Microcontroller 72 links to solid state relays (MOSFETs) 97 and 98 for controlling the provision of the 12 VDC power supply to fan 74, pump motor 83 and fill sensor 64, respectively.

As illustrated in Figure 1, once power switch 15 is depressed, a user employs keypad 16 and LCD 17 to select the operating parameters for wound closure apparatus 10. Wound closure apparatus 10 stores the previously selected operating parameters so that upon power initialization, LCD 17 displays the phrase "NEW PATIENT" with the word "NO" over arrow button 76, and the word "YES" over arrow button 77. If the user presses arrow button 76 to answer no, wound closure apparatus 10 will operate at the previously selected parameters. After answering no, the user presses on/off button 78 to begin operation of wound closure apparatus 10.

Conversely, if the user presses arrow button 77 to indicate a new patient, wound closure apparatus 10 will operate either under default values or allow the user to select the operating parameters. To operate under default parameters, the user presses on/off button 78 after pressing arrow button 77. However, to select his or her own values, the user presses option button 79 after pressing arrow button 77.

Upon the pressing of option buttons 79, LCD 17 displays a bar graph representing the spectrum of available vacuum pump pressures and a numerical representation of the vacuum pump pressure presently displayed by the bar graph. The user changes vacuum pump pressure using arrow buttons 76 and 77. The pressing of arrow button 76 reduces vacuum pump pressure, while the pressing of arrow button 77 increases vacuum pump pressure. After selecting the desired vacuum pump pressure, the user presses option button 79 to save the selected vacuum pump pressure.

Once the selected vacuum pump pressure has been saved, LCD 17 displays the pump operation times available to the user. The user may program wound closure apparatus 10 to pump either continuously or intermittently. Thus, LCD 17 displays the word "CONTINUOUS" over arrow button 76 and "INTERMITTENT" over arrow button 77. The user selects continuous operation by pressing arrow button 76 followed by on/off button 78 to activate the vacuum pump. In its continuous mode, wound closure apparatus 10 runs its vacuum pump continuously until on/off button 78 is pressed again.

If the user presses arrow button 77 to select intermittent operation, LCD 17 displays a bar graph or figures representing the minimum and maximum on times for the vacuum pump. LCD 17 also displays the phrase "ON TIME" and the numerical value presently displayed. A user decreases the on time of the vacuum pump by pressing arrow button 76 and increases the on time of the vacuum pump by pressing arrow button 77. After selecting the desired on time, the user presses options button 79 to save the selected on time value.

LCD 17 then displays a second bar graph or figures representing the off time for the vacuum pump with the phrase "OFF TIME" and the numerical value presently depicted by the bar graph. Again, arrow buttons 76 and 77 are pressed to increase or decrease, respectively, the off time for the vacuum pump. After selecting the off time, the user presses options button 79 followed by on/off button 78 to operate wound closure apparatus 10 using the selected parameters.

Keypad 16 includes setting button 80 to permit the user to sequentially display the currently selected operating parameters of wound closure apparatus 10. Keypad 16 further includes delay button 81 to permit the user to deactivate an alarm sounded in response to an improper operating condition of wound

closure apparatus 10. Delay button 81 provides the user with the ability to silence alarms so that the alarm will not have to be listened to during the correction of the problem.

Any new alarm conditions occurring within the fifteen minute period ("delay period") after the pressing of delay button 81 will not be indicated by an audible alarm. However, the pump will still be deactivated when appropriate, even during the delay period.

Again referring to Figure 9, microcontroller 72 is a multi-port microprocessor with a eight-bit analog to digital (A/D) converter having associated memory that stores the program directing microcontroller 72 during its control of wound closure apparatus 10. After receiving and storing the user selected operational parameters and receiving an on signal due to the pressing of on/off button 78, microcontroller 72 activates pump motor 83 which, in turn, drives vacuum pump 84 to begin the removal of air from canister 19.

As vacuum pump 84 operates, it draws air from within canister 19, into hose 62 via outlet 44 of canister 19 and port 45. Hose 62 connects to filter 85 and transducer 75 via T-junction 91. Filter 85 is similar to filter 46 and thus ensures no wound fluids contaminate vacuum pump 84. Filter 85 communicates with pump 84 via T-junction 88 and one arm of the latter is connected to bleed valve 86. Bleed valve 86 communicates with the atmosphere to release pressure developed within line 62 by vacuum pump 84 after microcontroller 72 deactivates vacuum pump 84. Bleed valve 86 is sufficiently small to ensure that it generally does not affect the vacuum pressure levels achieved by vacuum pump 84 as it evacuates air from canister 19, except to prevent over pressurisation beyond 250 mmHg and to prevent erratic operation of the vacuum pump at very low pressure settings..

In the preferred embodiment, an orifice of 0.5 mm diameter is especially preferred for bleed valve 86. Valve 86 or the equivalent is particularly important for enabling intermittent application of negative pressure, as the orifice allows for gradual release of the negative pressure (over a period of about fifteen seconds) when the pump motor 83 is de-actuated. Bleed valve 86 is positioned outside housing 11 to facilitate un-clogging of aperture 86 in the event of a blockage. An aperture is provided in bleed valve 86, which is machined from stainless steel. Flow control orifices would be alternatives.

Line 62 also includes T-connector 91 to connect it with line 92. Line 92 is connected to tank 94 which acts as a damper to pressure changes in line 62. This dampening effect, facilitated by restrictor 89 in line 93 between transducer 75 and T-junction 91, causes the pressure measured by transducer 75 to be an accurate indication of actual wound site pressure. Transducer 75 communicates with line 62 via line 93 to measure tank 94 pressure and produce an electrical signal representative of that pressure. Transducer 75 outputs its pressure signal to microcontroller 72.

Microcontroller 72 utilizes the pressure signal to control the speed of pump motor 83. As previously described, the user selects either a default vacuum pump pressure or a desired vacuum pump pressure for the operation of wound closure apparatus 10. After receiving the wound pressure signal from transducer 75, microcontroller 72 compares the wound pressure with the user selected pressure. If the wound pressure is higher than the user selected vacuum pump pressure, microcontroller 72 reduces pump motor speed to decrease vacuum pump pressure and thus the pressure at the wound. Conversely, if the wound pressure is less than the user selected vacuum pump

pressure, microcontroller 72 increases the speed of pump motor 83 resulting in an increase in the vacuum pressure applied at the wound.

Microcontroller 72 controls pump motor 83 by varying the amount of voltage received by pump motor 83. That is, microcontroller 72 receives the 12V DC signal from DC power supply 71 and outputs a voltage between 0 and 12V DC to pump motor 83 to control its speed in accordance with the user selected vacuum pump pressure value. Accordingly, microcontroller 72 employs feedback to ensure that the wound experiences the user selected vacuum pump pressure. If the target pressure is not reached after a period of five minutes, microcontroller 72 deactivates motor 83 and sounds the audible alarm. Additionally, the feedback signal prevents maximum vacuum pump pressure from being exceeded. If the wound pressure measured by transducer 75 exceeds a maximum safe vacuum pump pressure, microcontroller 72 deactivates pump motor 83.

Wound closure apparatus 10 includes fan 74 to cool pump motor 83 and printed circuit board or chassis 200 during the operation of the wound closure apparatus 10. In the preferred embodiment, microcontroller 72 controls fan 74 to always operate while power is being supplied. In alternative embodiments, however, microcontroller 72 controls fan 74 to operate only in relation to motor 83, because it is only necessary for fan 74 to operate if motor 83 is also operating. In such alternative, as long as pump motor 83 operates, microcontroller 72 runs fan 74. However, when microcontroller 72 deactivates pump motor 83 it also deactivates fan 74.

Control system 70 includes fill sensor 64 to provide a signal to microcontroller 72 that indicates when canister 19 is completely filled with wound fluids. After receiving a signal from fill sensor 64, microcontroller 72

deactivates pump motor 83 and fan 74 and activates alarm 95 to signal the user that canister 19 must be replaced.

Control system 70 includes switch 63 to prevent users from operating wound closure apparatus 10 without a canister properly installed. If a canister is not properly installed, switch 63 remains open and therefore outputs no signal to microcontroller 72. If microcontroller 72 receives no signal from switch 63, indicating no canister within chamber 18, it will not supply power to pump motor 83 even after a user has pressed on/off button 78. Furthermore, microcontroller 72 activates alarm 95 to signal the user that either a canister is not properly installed or is improperly installed within chamber 18 when therapy is activated. Microcontroller 72 operates pump motor 83 only if switch 63 is depressed to provide a signal indicating the proper placement of a canister within chamber 18.

Control system 70 includes tilt sensor 82 to prevent operation of wound closure apparatus 10 if it is tilted excessively. Excessive tilting of wound closure apparatus 10 during operation diminishes the efficiency of removal of wound fluids and, more importantly, might result in either the contamination of vacuum pump 84 or the spilling of wound fluids. Thus, if wound closure apparatus 10 tilts along any of its axes beyond a predetermined angle (approximately 45° in this preferred embodiment), tilt sensor 82 outputs a signal to microcontroller 72. In response, microcontroller 72 deactivates pump motor 83 and activates alarm 95 to signal the user of the excessive tilt situation. In this preferred embodiment, tilt sensor 82 may be implemented with any standard mercury switch. The tilt circuiting and alarm operates as follows. If therapy is in progress and the pump unit is tilted, the alarm will sound and the liquid crystal display 17 will state 'unit tilted'. Therapy is automatically stopped.

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When the unit is returned to the vertical, therapy will be automatically reinstated after a time delay (e.g. about 30 seconds) has elapsed..

CLAIMS:-

1. A therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad which is permeable to fluids for introduction into the wound, a dressing for covering the wound and providing an air-tight seal around the wound, a drainage tube connecting the pad to a suction pump so that negative pressure can be applied to the wound, to draw fluids therefrom, said tube being connected to the pump via a canister for collecting fluids sucked from the wound, and at least one filter being interposed between the canister and the pump.
2. Apparatus as claimed in claim 1 wherein said filter is located in the canister.
3. Apparatus as claimed in claim 1 or 2 wherein the canister is removably attached to a housing for the pump.
4. Apparatus as claimed in claim 3 wherein the canister is removably received in a recess in the housing.
5. Apparatus as claimed in any one of the preceding claims which includes means for detecting when said canister is substantially full with fluid.
6. Apparatus as claimed in claim 5 wherein said means comprises capacitance sensing means arranged to sense a change of capacitance as said canister fills with liquid.
7. Apparatus as claimed in any one of the preceding claims wherein said pad is a polymer foam having interconnecting cells.
8. Apparatus as claimed in claim 7 wherein the foam is a reticulated foam having at least 90% of interconnecting cells.
9. Apparatus as claimed in claim 8 wherein said foam has at least 95% of interconnecting cells.

10. Apparatus as claimed in claim 7, 8 or 9, wherein said drainage tube is fitted into the interior of the foam as an interference fit.
11. Apparatus as claimed in any one of claims 7 to 10 wherein said foam is a polyether foam.
12. Apparatus as claimed in any one of the preceding claims in which said dressing is an elastomeric film which is coated at least in the peripheral areas with a pressure-sensitive adhesive.
13. Apparatus as claimed in claim 12 wherein said film is a polyurethane film.
14. Apparatus as claimed in any one of the preceding claims which is adapted to apply continuous or intermittent suction to the wound.
15. Apparatus as claimed in claim 14 wherein a bleed device is provided between the canister and the pump to permit release of negative pressure during intermittent operation.
16. A sterile pack for use in conjunction with a vacuum pump and canister for stimulating wound healing by drainage, said pack comprising a polymer foam pad of reticulated open-celled foam having a drainage tube sealed within the foam.
17. A pack as claimed in claim 16 wherein said foam comprises more than about 95% interconnecting cells.
18. A pack as claimed in claim 16 or 17 which includes connector means for connecting the tube to said canister or to a tube attached to said canister.
19. A pack according to any one of the preceding claims wherein the tube is fitted into the foam by an interference fit.

20. A canister for use in the apparatus as claimed in any one of claims 1 to 15 which comprises a moulded plastics container having an inlet for connection to a wound dressing pad and an outlet for connection to a suction pump, said outlet incorporating a bacterial filter.

21. A canister as claimed in claim 20 which includes deflector means for deflecting liquid sucked through the inlet in a direction towards the bottom of the canister.

22. A canister as claimed in claim 20 or 21 which includes an anti-foaming substance.

23. A canister as claimed in any one of claims 20 to 22 which includes a gel-forming substance, which is capable of immobilising drainage fluids within the canister.

24. Therapeutic apparatus is claimed in any one of the preceding claims which includes a tilt sensor adapted to give an audible and/or visual alarm when the apparatus is tilted beyond a predetermined angle from vertical.

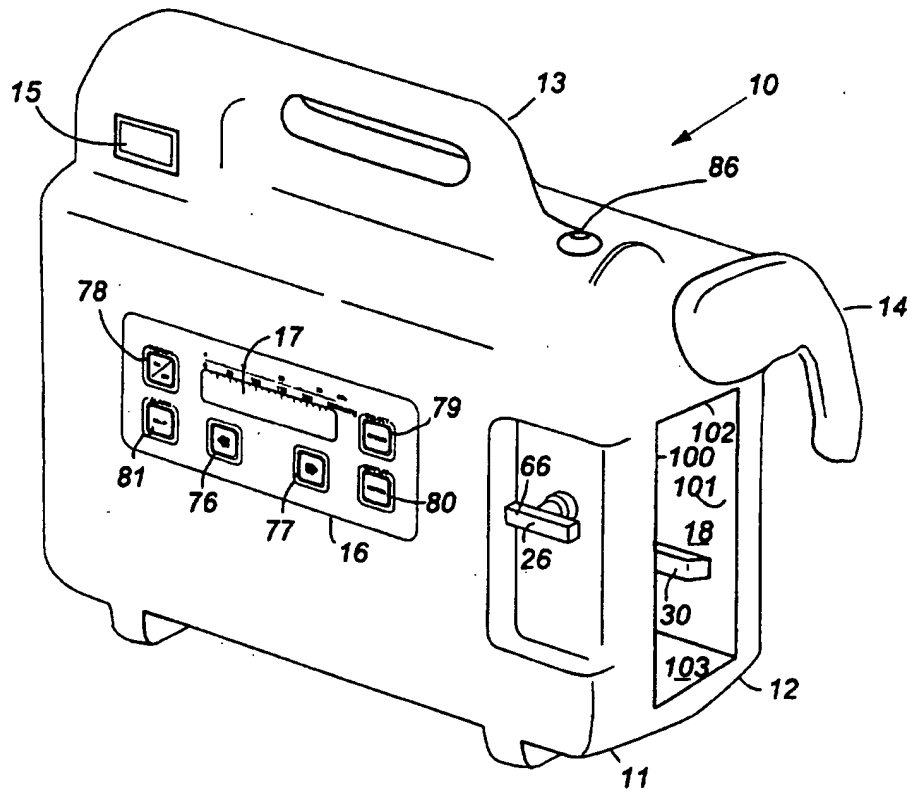


FIG.1

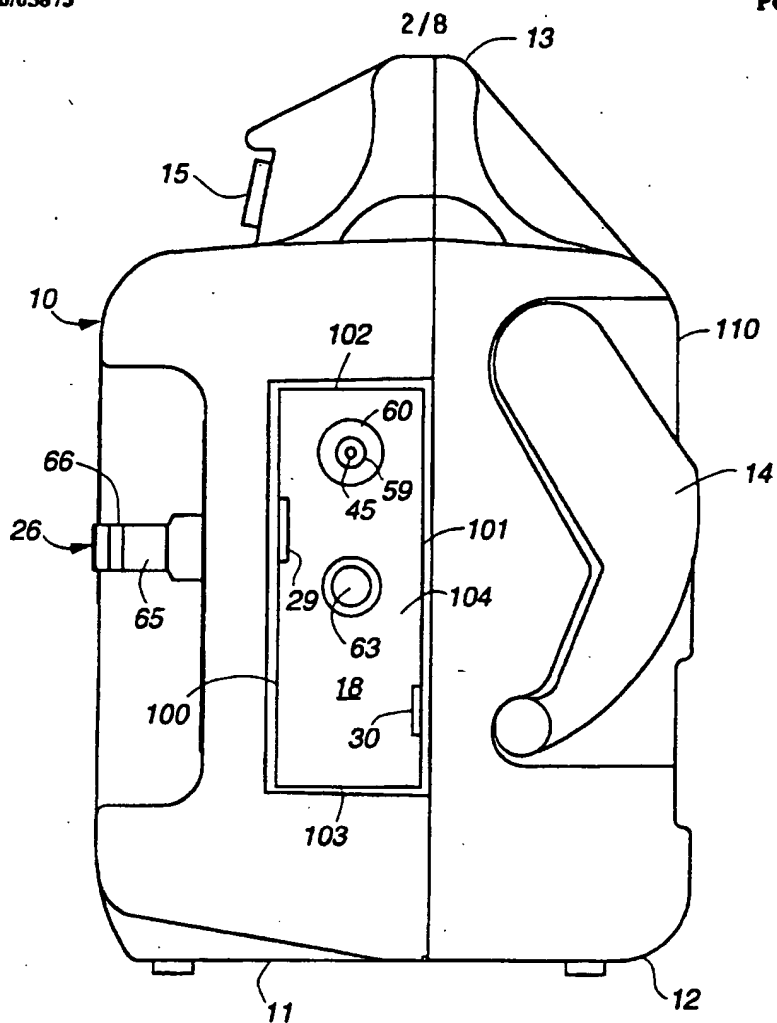


FIG.2

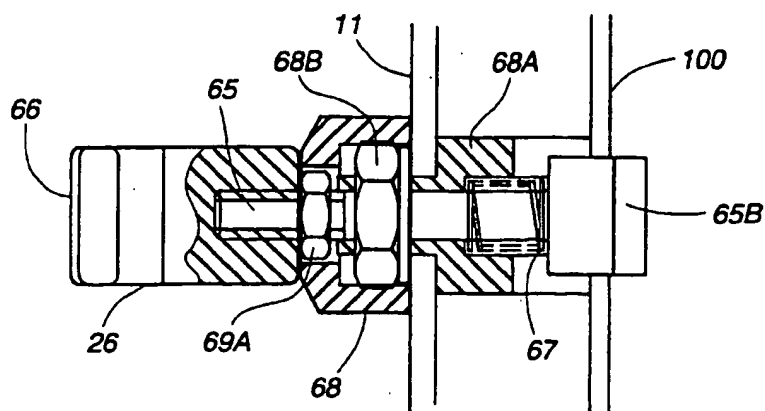


FIG.2A

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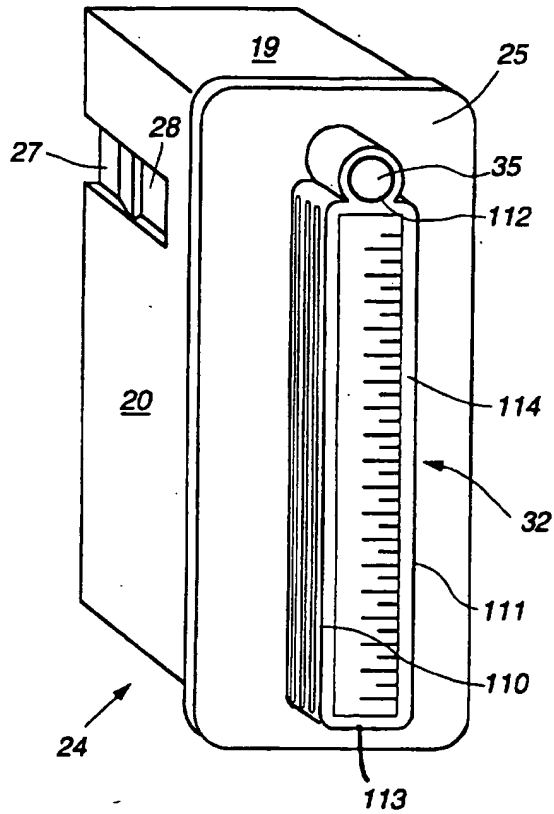


FIG.3

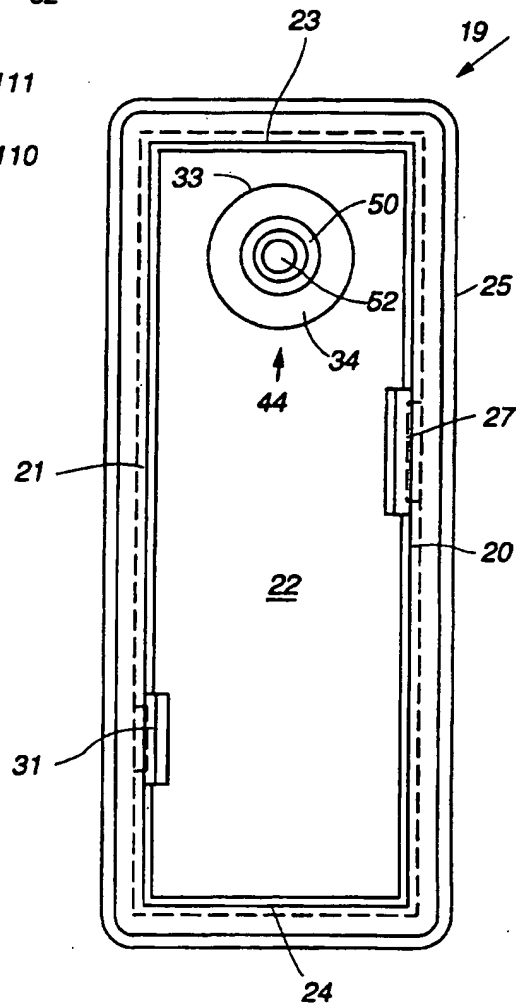


FIG.4

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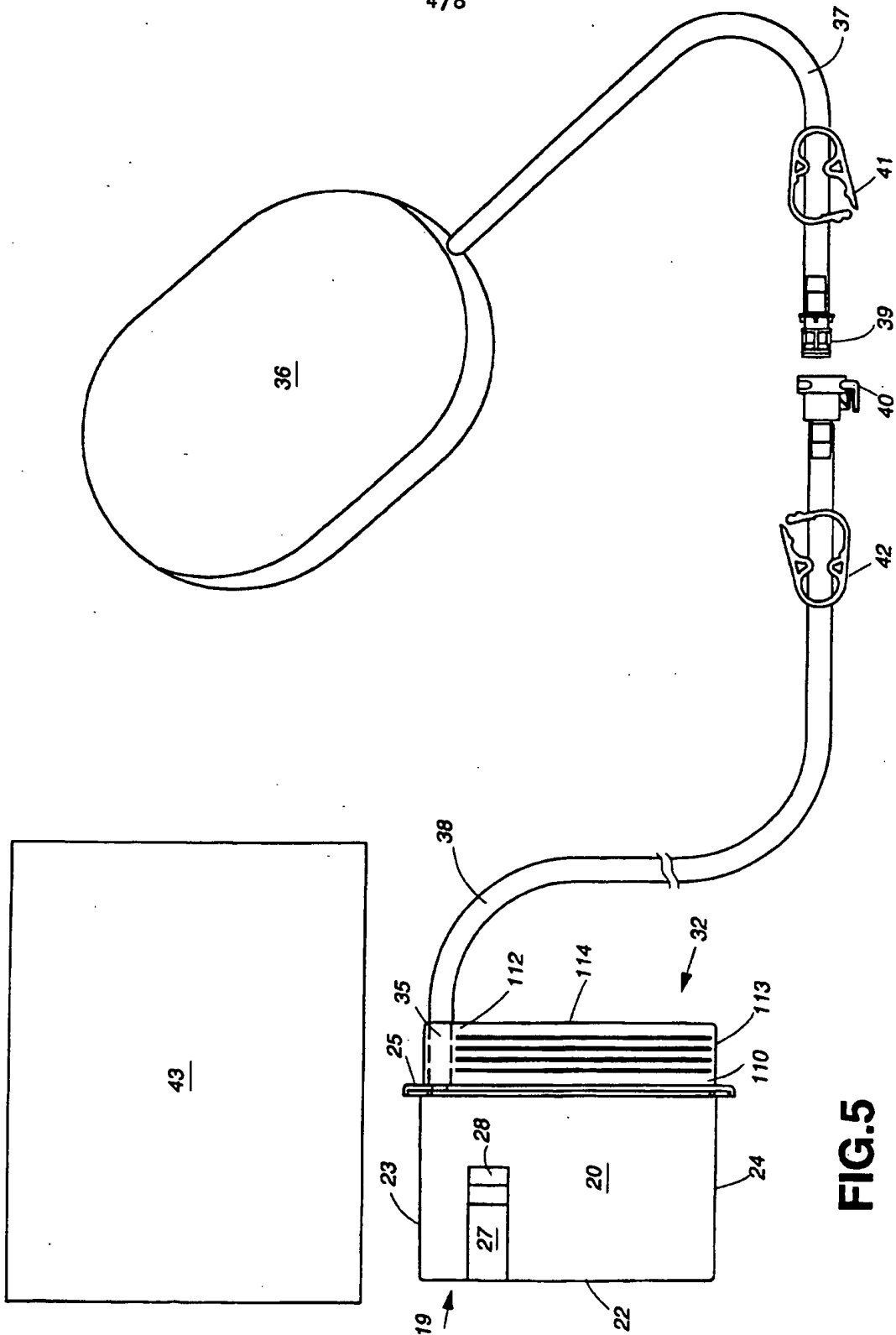


FIG. 5

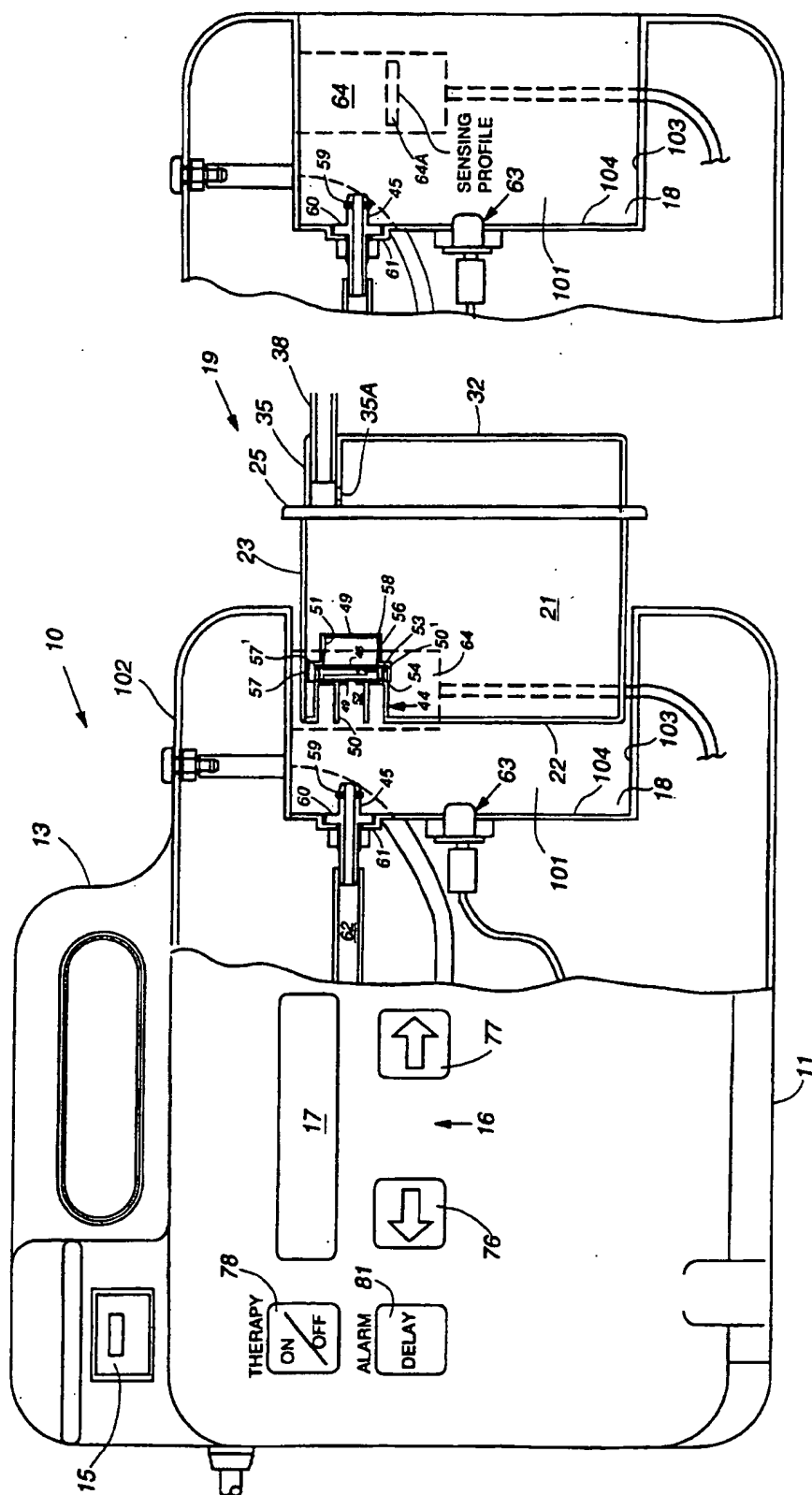


FIG.6A

FIG.6

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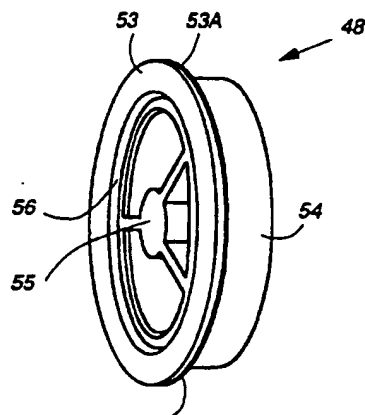


FIG. 7

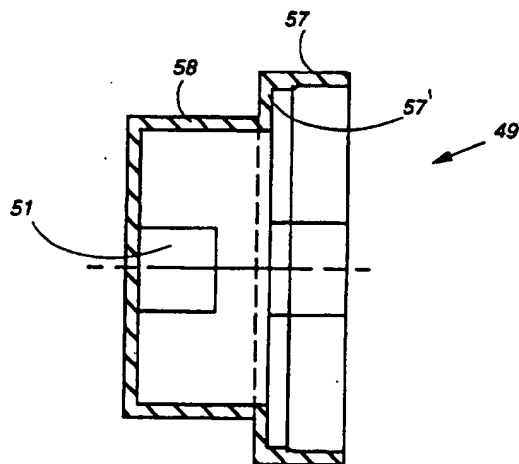


FIG. 8

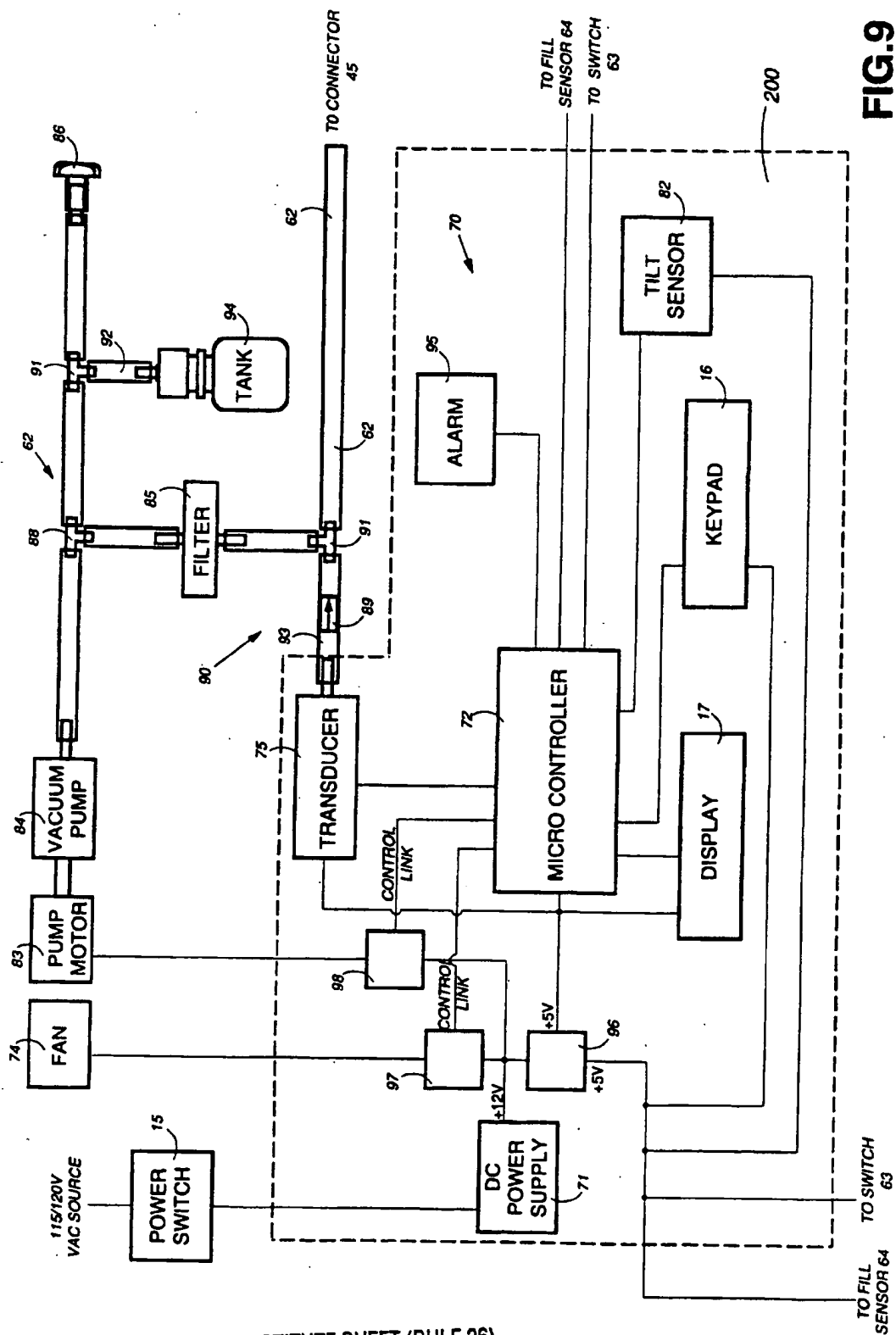


FIG.9

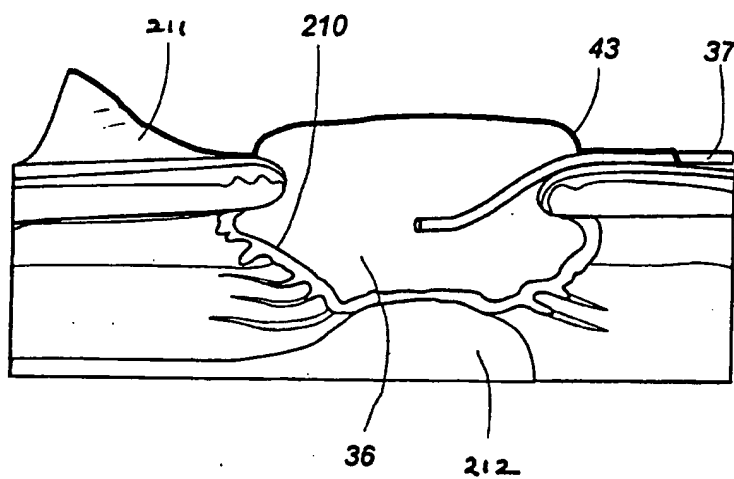


FIG.10

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 95/01983

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,3 520 300 (FLOWER GUILLES JR) 14 July 1970	1,7-13, 16-19
Y	see column 2, line 10 - column 3, line 16; figures	2-6,14, 15,22-24
Y	US,A,4 758 220 (SUNDBLOM LEIF J ET AL) 19 July 1988	3,4,14, 15
A	see abstract; figures 3,6A see column 5, line 3 - line 34 see column 12, line 48 - line 50	5
Y	DE,A,26 40 413 (WOLF GMBH RICHARD) 9 March 1978 see claims 1,6,7; figure 1	5,6
A	US,A,5 279 550 (HABIB MAGDI F ET AL) 18 January 1994 see abstract; figures 1,3	15

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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

9 November 1995

Date of mailing of the international search report

23. 11. 95

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Zeinstra, H

INTERNATIONAL SEARCH REPORT

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PCT/GB 95/01983

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 215 522 (PAGE ET AL.) 1 June 1993 see abstract; figures 1-3 see column 1, line 55 - line 68 ---	16
X	EP,A,0 358 302 (SMITHS INDUSTRIES PLC) 14 March 1990	20,21
Y	see abstract; figures 1,4	2,22,23
A	see column 2, line 26 - column 4, line 34 ---	1
Y	GB,A,2 197 789 (SMITHS INDUSTRIES PUBLIC LIMITED COMPANY) 2 June 1988 see abstract; figures see page 5, line 1 - line 13 ---	22
Y	US,A,5 092 858 (BENSON C DAVID ET AL) 3 March 1992 see abstract; figures 1-6 see column 4, line 33 - column 5, line 27 ---	23
Y	PATENT ABSTRACTS OF JAPAN vol. 016 no. 394 (C-0976) ,21 August 1992 & JP,A,04 129536 (TERUMO CORP) 30 April 1992, see abstract ---	24
A	WO,A,93 09727 (WAKE FOREST UNIVERSITY) 27 May 1993 cited in the application -----	

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. .onal Application No
PCT/GB 95/01983

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-3520300	14-07-70	NONE	
US-A-4758220	19-07-88	US-A- 4790816 US-A- 4810242	13-12-88 07-03-89
DE-A-2640413	09-03-78	FR-A, B 2364036 GB-A- 1574066	07-04-78 03-09-80
US-A-5279550	18-01-94	NONE	
US-A-5215522	01-06-93	US-A- 4569344 US-A- 4638539 US-A- 4696296 US-A- 5277177 US-A- 4836199 US-A- 4872579	11-02-86 27-01-87 29-09-87 11-01-94 06-06-89 10-10-89
EP-A-0358302	14-03-90	GB-A- 2220357	10-01-90
GB-A-2197789	02-06-88	NONE	
US-A-5092858	03-03-92	NONE	
WO-A-9309727	27-05-93	AU-A- 3130393 CA-A- 2121688 EP-A- 0620720 JP-T- 7501958	15-06-93 27-05-93 26-10-94 02-03-95

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